

REMARKS

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, 110, 111, and 112 are pending, with claim 94 being the only withdrawn claim. By this amendment, claims 26 and 52 have been amended, and new claims 111 and 112 have been added. The amendments to claims 26 and 52 and the addition of claims 111 and 112 are made pursuant to a September 28, 2011 telephone conference between Examiner Lezah Roberts and applicant's undersigned attorney, Barry I. Hollander, and as discussed with the Examiner, are supported in the present application at, for example, page 22 line 12 to page 23 line 14. No new matter has been introduced.

The election of species remains: (1) durum wheat as the plasticized matrix material, (2) a probiotic nutraceutical component as an encapsulant, (3) starch as the additional matrix material, and (4) liquid encapsulant as the encapsulant form. The claims readable on the elected species are Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, 109, and 110, and new claims 111-112.

Telephonic Interviews

Applicant thanks Examiner Lezah Roberts for the courtesy of an Examiner-Initiated telephonic interview on September 19, 2011 and a follow-up telephonic interview on September 28, 2011 with applicant's undersigned attorney Barry I. Hollander.

During the September 19, 2011 telephonic interview, the Examiner indicated that she was considering allowing the application, and suggested that applicant consider the inclusion of conditions in the claims which resulted in the starch not being substantially destructured or dextrinized, such as reciting a temperature range or low shear rate. The Examiner also advised that she had updated her search, for the possible allowance, and located U.S. Patent No. 4,911,952 to Doane et al. The Examiner requested applicant's comments as to the meaning of destructured and the pertinency of the Doane et al reference. As to the meaning of destructured, the undersigned advised the Examiner that EP0400531 to

Bastioli et al provides a definition of destructured starch, and the Examiner located a patent family member, U.S. Patent No. 5,462,982 to Bastioli et al.

During the September 28, 2011 telephone conference the undersigned proposed amendments as now presented in new claims 111 and 112, and provided support therefor in the specification, and the Examiner requested the present amendment of claims 26 and 52. Additionally, the Examiner was advised that the Doane et al patent teaches substantial destructure of starch, and does not teach or suggest production of a product as claimed where the starch is not substantially destructured or dextrinized. As discussed with the Examiner, Doane et al teaches complete starch granule rupture. Doane et al discloses that the starch is prepared for encapsulation by thorough dispersion in water under conditions that completely disrupt the starch granules and completely disassociate essentially all the amylose molecules without significant depolymerization. According to Doane et al, the dispersion is accomplished with starches having amylose contents of up to about 25% when an aqueous slurry of the starch is passed through a steam-injection cooker at a temperature of about 120°C-135°C, and starches having greater than about 25% amylose require temperatures of about 155°C-160°C. It is disclosed that gelatinization at lower temperatures does not allow complete granule rupture, while gelatinization at higher temperatures causes some starch depolymerization. Steam-injection cooking is a preferred method of gelatinization because it affords the advantage of providing a continuous process and because disruption of starch granules is accomplished rapidly and completely in one step. Alternatively, it is disclosed, extrusion cooking will effectively achieve the gelatinization. See col. 2 lines 65 to col. 3 line 15 and col. 7 lines 13-25.

It was pointed out that Bastioli et al discloses that as a result of heat treatment carried out at a temperature higher than the glass transition temperatures and the melting points of the components, fusion occurs and the molecular structure of the starch granules become disordered, producing so-called "destructured starch". In the Bastioli et al process, starch is mixed in a heated extruder, with a high-boiling plasticizer and a destructuring agent selected

from the group consisting of urea, alkaline and alkaline-earth hydroxides, and mixtures thereof for a time sufficient to bring about the destructuring, and at a temperature below the boiling point of the plasticizer and between 120°C and 170°C, preferably between 140°C and 170°C, which is consistent with the temperature range disclosed by Doane et al.

Furthermore, Bastioli et al discloses that from a microphotograph relating to their comparative experiment 1, it is apparent that the extrusion temperature of 100° C. is too low and does not allow the destructuring of the starch because the microphotograph shows the presence of a large number of still intact starch granules. The analysis, it is disclosed, of the product obtained from example 2 (extrusion temperature 120°C.) shows that the number of intact starch granules has been substantially reduced, although some are still present. On the other hand, it is disclosed, a complete destructuring of the starch is obtained according to example 3 with an extrusion temperature of 140°C. The microphotographs obtained from the material of example 3 does not show intact starch granules according to Bastioli et al.. See Bastioli et al U.S. Patent No. 5,462,982 at col. 1 lines 24-36, col. 2 lines 20-41, and col. 4 lines 7-27.

The present application discloses embodiments where there is substantial gelatinization of starch, without substantial destructuring or dextrinization of starch, even using temperatures which may overlap with those employed by Doane et al. As disclosed in the present specification, and as discussed further below, temperature is not the only parameter affecting dextrinization and destructurization of starch. As disclosed in the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 7 and 8, the paragraph bridging pages 12 and 13, the paragraph bridging pages 22 and 23 to page 23 second full paragraph, and the first full paragraph on page 26, low shear mixing, low temperature and plasticizer amounts, amount of amylose, amount of amylopectin, and extrusion residence time, screw speeds, and screw configuration are employed to achieve plasticization without substantial destructurization or dextrinization of the starch.

During the September 28, 2012 telephonic interview, the Examiner advised that she would speak to her supervisor regarding withdrawal of the rejections, the proposed claim amendments, and whether prosecution would be reopened in view of the Doane et al reference.

Applicant notes with appreciation that in view of the Appeal Brief filed on July 1, 2011, prosecution has been reopened, the rejections under 35 U.S.C. 112, first and second paragraphs, have been withdrawn, and the 35 U.S.C. 103(a) rejections over Newton et al (U.S. Patent No. 4,938,967) in view of Eden et al (U.S. Patent No. 4,755,397) alone, and in further view of Jane et al (U.S. Patent No. 5,397,834) have been withdrawn. The Examiner has not applied the Doane et al reference but has made new rejections under 35 U.S.C. 103(a) in the present non-final Office Action involving newly cited Schiltz (US 5,449,708), Farquharson et al (US 4,888,174), Loomis et al (US 5,852,114), Tye et al (US 5,308,636), Fishman et al (US 5,451,673), and Desaga DE 19503993, and previously cited Newton et al (US 4,938,967).

Applicant respectfully requests the Examiner to cite U.S. Patent No. 4,911,952 to Doane et al, EP0400531 to Bastioli et al, and its patent family member, U.S. Patent No. 5,462,982 to Bastioli et al. A Supplemental Information Disclosure with a form PTO-1449 listing those references is being filed concurrently herewith.

THE REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 25, 26, 28, 30, 31, 35, 37 40, 46, 91, 92, 101, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Schiltz (US 5,449,708) in view of newly cited Farquharson et al (US 4,888,174). This rejection is respectfully traversed.

Neither Schiltz nor Farquharson et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent

claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious. Schiltz discloses a method for the continuous preparation of a starch-based biodegradable polymer. A homogeneous mixture of starch, an ethylene acrylic acid co-polymer, and a salt of stearic acid are premixed before addition of an aqueous lubricant material. An increase in temperature gelatinizes the starch and melts the co-polymer. Excess moisture is removed under reduced pressure and a plastic material is extruded. The starch is gelatinized prior to and during dispersion within the ethylene acrylic acid copolymer and, optionally, polyethylene. According to Schiltz, "Gelatinization disrupts the starch granules, providing access to individual starch molecules. Extensive gelatinization is critical for compatibility of the starch with the copolymer component and, later, with respect to biodegradability." An aqueous solution of lubricant, having a preferred pH, with the appropriate temperature and sheer forces, is employed to effect the desired degree of gelatinization. The Schiltz gelatinization "disrupts the starch granules and provides access to individual starch molecules to compatibilize the starch for use in the plastic material, and at the same time increase biodegradation. See the abstract, paragraphs bridging columns 3 and 4, col. 4 lines 4 to 45, col. 5 lines 1-10 col. 6 lines 37-46 col. 8 lines 14-36. Schiltz clearly wants to destroy the starch granules so that the individual starch molecules or amylose can interact with the copolymer and polyethylene to form a polymer composite.

The Examiner asserts that it is reasonable to conclude that the starches used by Schiltz are not substantially dextrinized or substantially destructured because Schiltz discloses temperature ranges up to 135°C, similar to those disclosed by the instant specification up to 160°C and below the decomposition of starch. However, temperature is not the only parameter affecting dextrinization and destructure of starch. As disclosed in the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 7 and 8, the paragraph bridging pages 12 and 13, the paragraph bridging pages 22 and 23 to page 23 second full paragraph, and the first full paragraph on

page 26, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration are employed to achieve plasticization without substantial destructurization or dextrinization of the starch. For example, applicant discloses:

...The controlled release or delayed release composition may be produced without substantial expansion of the matrix material to thereby avoid production of a low density product which prematurely or too rapidly releases the encapsulant or the embedded component. The products may be produced using low shear mixing to avoid decomposition of the matrix material and encapsulant or active component. However, even though low shear mixing is utilized, substantial plasticization of the matrix material and at least substantially uniform distribution of the active component are achieved. (Emphases Added, paragraph bridging pages 6 and 7)

....The matrix material is plasticized upon heating to form a melt. The active component is admixed with the melt without substantially deleteriously affecting or decomposing the encapsulant or the matrix material. The active component is admixed with the plasticized matrix material at low temperatures and under low shear mixing conditions to thereby avoid substantial destruction of or volatilization of active components. Additionally, high water contents may be employed so as to substantially reduce viscosity and facilitate substantial gelatinization of the starch without substantially destroying the starch molecules. (Emphases Added, paragraph bridging pages 7 and 8.)

Schiltz does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Schiltz employs a critical pH of 10-12, preferably accomplished with the addition of sodium hydroxide, to disrupt the starch granules and provide access to individual starch molecules to achieve interaction between the components to obtain a polymer composite. See col. 8 lines 14-36.

The Examiner maintains that Farquharson et al discloses a composition comprising an insecticide and a polymer, the compositions may be formulated into films, and the

compositions may be incorporated into polymer pellets, with the size of the pellet ranging in diameter from about 1/16 to about 1/2 inch (1.58 mm to 12.7 mm). It is asserted that it would have been obvious to one of ordinary skill in the art to have made the pellets of Schiltz a size where the diameter ranges from 1/16 to 1/2 inch motivated by the desire to make pellets a size disclosed by the art as suitable for pellets used in agriculture.

Farquharson et al does not cure the above-discussed deficiencies in the disclosure of Schiltz. Farquharson et al discloses that it has been unexpectedly discovered that the addition of relatively small amounts of selected 3 to 5 carbon atom carboxylic acid comonomers, such as acrylic acid or methacrylic acid, to certain polymer blends containing an O-pyridyl phosphate insecticide will significantly retard the migration of the O-halopyridyl phosphate insecticide from such polymers, thus maintaining the ability of articles, including films, formed from such polymers to control insects over a longer period of time. The compositions are prepared by dry blending together low-density polyethylene and a copolymer such as ethylene/acrylic acid, and then by adding the O-halopyridyl phosphate insecticide, the UV stabilizer and the pigment. The dry blend is heated to a temperature below the melting temperature of either polymer in the blend but above the melting point of the O-halopyridyl phosphate insecticide to absorb the said insecticide onto the polymer blend. The composition thus formed can be extruded into articles such as pellets, sheets, films, bags or shrouds. See col. 1 line 55 to col. 2 line 21, and col. 6 lines 1-14. The reference does not disclose the use of starch or avoiding destructureization or dextrinization of starch. Even if the pellet sizes employed by Farquharson et al were used in the process of Schiltz, applicant's claimed invention would not be obtained or rendered obvious.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Loomis et al (US 5,852,114) in view of previously applied Newton et al (US 4,938,967). This rejection is respectfully traversed.

Neither Loomis et al nor Newton et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner maintains that Loomis et al discloses biodegradable thermoplastic polymer blends comprising a first polymer and a second polymer which form a homogeneous blend where the first polymer includes hydrophobic polymers and may comprise 20% to 80% by weight of the total composition, and the polymers may also include polyvinyl pyrrolidone. According to the Examiner, the second polymer ranges from about 10% to 70% by weight of the total composition and includes polyvinyl acetate copolymers, pectins, polysaccharides, starch, cellulose and alginates, and a starch component is also incorporated into the composition to impart further desirable physical properties and characteristics. However, the pectins, polysaccharides, starch, cellulose and alginates, and a starch component are not disclosed as the second polymer, but rather may be added to the first and second polymers. See col. 8 lines 4-14. The Examiner indicates that the starch component includes native or granular starch, chemically modified starch, gelatinized starch and destructured starch and combinations thereof.

The Examiner asserts that Loomis et al discloses temperature ranges from 120 to 180°C at col. 3, lines 3-8, similar to those disclosed by the instant specification up to 160°C, so therefore it is reasonable to conclude that the starches used by Loomis et al are not "substantially dextrinized". However, no such disclosure is seen in Loomis et al. Loomis

discloses the use of extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and the extruder die. See col. 14 lines 30-54.

Moreover, applicant's claims recite that the starch is not substantially destructured. Loomis desires destructured starch and employs extrusion conditions to destructure starch. According to Loomis et al, "when starch is heated under shear in the presence of relatively small amounts of water, the resulting new starch-water composition, in the form of a melt, surprisingly has thermoplastic properties. Those thermoplastic starch compositions have become known as "destructured starch." See col. 2 lines 16—26. Loomis et al produces polymer blend compositions that are thermoplastic. See col. 1 lines 16-20. Loomis et al may include destructured starch in the compositions to impart further desirable physical properties and characteristics. See col. 4 lines 59-67. If starch or gelatinized starch was employed, it would be subjected to the intense extrusion conditions which would destructure the starch. As disclosed by Loomis et al:

In compositions prepared from a first polymer, a second polymer and a polysaccharide component, such as a starch component, the starch component may be processed--e.g., gelatinized or destructured--independently from the first polymer and the second polymer, and then included in, or added to, the composition either before or after processing the components used to form the composition. Alternatively, the starch component may be included in the composition while processing the first polymer and the second polymer into the uniform, substantially homogeneous uniform blend. See col. 11 lines 16-25.

In accordance with the present invention, the compositions may be prepared by subjecting the components used to form the inventive compositions to conditions of intensive mixing, with elevated temperature, such as the conditions that are achieved within the screw and barrel of an extruder. The first polymer and the second polymer, and optionally a polysaccharide component, such as a starch component, may be introduced to intensive mixing conditions in the form of granules, pellets or powders, or in a plasticizer as slurries or solutions thereof. (Emphases added.) See col. 11 lines 38-49.

Processing under the intensive mixing conditions described herein should be continued at a temperature that is greater than the melting point of the first polymer, which itself is typically lower than the melting point of the second polymer, and for a time sufficient to cause the first polymer and the second polymer (and other optional components) to become intimately associated by way of blending to form a uniform, substantially homogeneous blend, and under appropriate conditions a melt-blend. (Emphasis Added). See col. 12 lines 22-30.

Also, as discussed above, Loomis employs extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and die, and also a very high a L/D of 38, and the removal of any water in the first zone of the extruder, all of which would result in destructuring of starch. See col. 14 lines 18-54.

As discussed above, and as discussed in the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 7 and 8, the paragraph bridging pages 12 and 13, the paragraph bridging pages 22 and 23 to page 23 second full paragraph, and the first full paragraph on page 26, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration are employed to achieve plasticization without substantial destructurization or dextrinization of the starch.

Loomis et al does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Loomis et al employs high extrusion temperatures, a high L/D, intensive mixing conditions, and low moisture contents to obtain destructured starch and a thermoplastic composition.

The Examiner maintains that Newton et al discloses applicant's density as conventional, the amount of active ingredient, pellet size, and coatings and it would be obvious to modify the Loomis et al compositions in accordance with the teachings of Newton et al. The Examiner admits that Newton et al does not disclose the use of a

plasticized mass comprising starch. Newton et al does not cure the above-discussed deficiencies in the disclosure of Loomis et al. Even if the references were properly combinable, employment of a starch binder of Newton et al in the process and composition of Loomis et al would still result in substantial destructure of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 42, 69, 70, 84 and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Loomis et al (US 5,852,114) in view of previously applied Newton et al (US 4,938,967) as applied to claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 in further view of newly cited Tye et al (US 5,308,636). This rejection is respectfully traversed.

The comments above regarding Loomis et al and Newton et al are applicable here and incorporated herein. Tye et al does not cure the deficiencies in the disclosures of Loomis et al and Newton et al discussed above. Even if all three references were properly combinable, applicant's claimed invention would not be obtained or rendered obvious. None of the references, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized.

The Examiner admits that Loomis et al and Newton et al do not disclose the use of durum wheat as a source of starch. The Examiner maintains that Tye et al discloses gellable starch based systems, and the starches include wheat sources such as semolina flour in Example 5. It is asserted that it would have been obvious to one of ordinary skill in the art to have used wheat durum (semolina flour) as the wheat starch in the compositions of the combined teachings of Loomis et al in view of Newton et al motivated by the desire to use a wheat starch suitable for making gellable compositions that can be ingested as disclosed by Tye et al. However, Loomis et al does not disclose the production of gellable compositions

and it is not seen why one ordinarily skilled in the art would modify the Loomis et al composition to be gellable. Additionally, neither Loomis et al nor Newton et al employ a flour, and there is no reason to employ a flour in the Loomis et al product when all that is needed is a starch. Moreover, even if the references were properly combinable, employment of semolina of Tye et al in the process and composition of Loomis et al would still result in substantial destructure of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over previously applied Newton et al (US 4,938,967) in view of newly cited Fishman et al (US 5,451,673). This rejection is respectfully traversed.

Neither Newton et al nor Fishman et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner employs Newton et al as teaching pharmaceutical compositions. Newton et al employs a weighting agent to increase density beyond normal levels to thereby increase release time. The weighting agent generally is employed in an amount of at least 50% by weight of the unit, and generally has a density of at least 2.5 g/ml. The weighting agent may be a powder such as barium sulphate, ferric oxide, ferrum redactum, titanium dioxide and aluminum oxide or hydroxide, calcium carbonate, barium phosphate, bismuth phosphate, calcium aluminosilicate, zirconium silicate, calcium phosphate, silicon carbide, and magnesium carbonate. See col. 4 lines 33-52, col. 5 lines 7-9, and col. 9 line 43 to col. 10 line 1.

Newton et al discloses the use of a conventional matrix binder which may be a synthetic polymer or natural polymer or derivative such as starch or preferably cellulose or its derivatives. A known gastric controlled release binder may also be employed such as hydrophobic acrylic polymers or cellulose derivatives, vinyl polymers and other high molecular weight natural polymer derivatives or synthetic polymers. See col. 8 line 61 to col. 9 line 36. Each unit may comprise a homogeneous or non-homogeneous blend of the active ingredient and the weighting agent and any matrix binder component. For instance each unit may have a core of weighting agent covered by a shell of active ingredient or vice versa or it may be formed of a blend of the active ingredient and the weighting agent. See col. 10 lines 58-64. The preferred method for forming the pellets or other units is to make a mixture of the weighting agent and the active ingredient and matrix binder and then to form the mixture into the units. Generally some water is added to the mixture to aid pelletization. See col. 11 lines 34-44.

The Examiner admits that Newton et al does not teach a plasticized matrix. It is asserted that the secondary reference, Fishman et al, discloses a heated plasticized matrix and it would have been obvious to one skilled in the art to have used the heated plasticized matrix of Fishman et al in the formulations of Newton et al, motivated by the desire to use a composition that is suitable for carriers and encapsulation materials. However, Newton et al already discloses use of a carrier that includes a gastric controlled release binder that will permit controlled release of the active ingredient from the controlled release unit while in the stomach, and the controlled release unit has a critical density of at least 2 g/ml. See col. 4 lines 42-52, and col. 5 lines 7-9. There is no reason to employ the composition of Fishman et al in the Newton et al formulation.

The Examiner maintains that Fishman et al discloses temperature ranges up to 200°C similar to those disclosed by the instant specification up to 160°C, and therefore it is reasonable to conclude that the starches used by Fishman et al are not "substantially dextrinized" or "substantially destructured". To the contrary, Fishman et al teach that the

“gelatinized starch solution is prepared by mixing starch with water and heating it above the boiling point of water under pressure for a sufficient time to break down starch granules.” (Emphasis added.) See col. 5, lines 1-4.

As discussed above, and as discussed in the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 7 and 8, the paragraph bridging pages 12 and 13, the paragraph bridging pages 22 and 23 to page 23 second full paragraph, and the first full paragraph on page 26, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration are employed to achieve plasticization without substantial deconstructurization or dextrinization of the starch.

Even if the references were properly combinable, employment of a pectin and starch film forming composition of Fishman et al in the process and composition of Newton et al would still result in substantial deconstructurization of the starch because it would be subjected to Fishman et al’s heating above the boiling point of water under pressure for a sufficient time to break down starch granules.

Additionally, claims 34 and 61 recite a density of 800 g/liter to 1500 g/liter (0.8 to 1.5 g/ml) whereas according to Newton et al at col. 5 lines 7-9, a higher density of above about 2 g/ml (2000 g/liter) is critical to Newton et al for achieving an increased residence time in the stomach. It would be contrary to the disclosure of Newton et al to modify the composition to obtain applicant’s claimed density.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 25, 26, 28, 30, 31, 35, 37, 38-40, 46, 50, 52, 53, 55, 56, 58, 59, 62, 64-67, 69, 73, 75, 79, 81, 83, 91-93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Desaga (DE 19503993) in view of newly cited Loomis et al (US 5,852,114). This rejection is respectfully traversed.

Neither Desaga et al nor Loomis et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner maintains that Desaga discloses compositions for supplying food ingredients or drug substances for improvement of glucose intolerance, insulin resistance or hyperlipidemia in obesity, where active ingredients include an omega-3 fatty acid with a content of at least 5% and an additional ingredient such as medium chain triglycerides with a content of at least 5%, the fatty acid includes fish oil and is dispersed in a plasticized starch matrix, and the starch products include cyclodextrins, native or modified starches.

The Examiner admits that Desaga does not disclose the amount of matrix material in the compositions or that the starch is not substantially destructured or dextrinized. The Examiner alleges that it would have been obvious to one of ordinary skill in the art to have made the pellets of Desaga with the plasticized matrices comprising starch of Loomis et al motivated by the desire to use a plasticized starch matrix suitable for delivering pharmaceuticals. In regard to the starch not being substantially dextrinized or destructured, the Examiner asserts that the starch may be a gelatinized starch which is disclosed as different from destructured starch, meeting the limitation of not substantially dextrinized or destructured.

However, as discussed above, Loomis et al employs extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and die, and also a very high a L/D of 38, and the removal of any water in the first zone of the extruder, all of which would result in destructuring of starch. See col. 14 lines 18-54.

As discussed above, and as discussed in the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 7 and 8, the paragraph bridging pages 12 and 13, the paragraph bridging pages 22 and 23 to page 23 second full

paragraph, and the first full paragraph on page 26, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration are employed to achieve plasticization without substantial destructurization or dextrinization of the starch.

Loomis et al does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Loomis et al employs high extrusion temperatures, a high L/D, intensive mixing conditions, and low moisture contents to obtain destructured starch and a thermoplastic composition.

Even if the references were properly combinable, employment of the plasticized starch of Loomis et al in the process and composition of Desaga would result in substantial destructurization of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In light of the foregoing amendments and remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

It is not believed that any additional fees are due. However, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary

U.S. Application No. 09/782,320
Bernhard van Lengerich
AMENDMENT UNDER 37 C.F.R. 1.111
And Record of Telephonic Interview
Attorney Docket No. BVL-102A

or to credit any overpayments to Deposit Account No. 19-0089 (P32853).

Respectfully submitted,
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